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Randomised single blind patient controlled trial of VNUS closure compared with groin dissection and long saphenous vein (LSV) stripping for recurrent varicose veins

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 26/08/2008	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0192119061

Study information

Scientific Title

Study objectives
To determine whether VNUS is as effective as groin re-exploration for recurrent varicose veins in association with a recurrently incompetent long saphenous vein (LSV). Assessment will be by Duplex scan at 6 weeks, 1 year and 5 years.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular: Recurrent varicose veins

Interventions
VNUS closure compared with groin dissection and long saphenous vein (LSV) stripping for recurrent varicose veins

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Operative time, visual analogue scales for pain and bruising, costs of procedure, recurrence rates.

Secondary outcome measures
Not provided at time of registration

Overall study start date
31/07/2002

Completion date
12/12/2004

Eligibility

Key inclusion criteria
Age 18-80

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Not Specified

Target number of participants
60

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
31/07/2002

Date of final enrolment
12/12/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Vascular Surgery
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Queen's Medical Centre University Hospital NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2006		Yes	No